

## **REMARKS**

Claims 1-52, 69-77, 80-82, 84-92, and 96-102 are pending in the present application. Claims 1-98 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. New claim 103 has been added. No new matter enters by way of the foregoing amendment. Upon entry of the foregoing amendment, claims 99-103 will be pending.

Claims 1-52, 69-77, 82, 84, 101, and 102 were previously withdrawn from consideration. Because claims 101 and 102 depend from generic claim 99 that is believed to be allowable, Applicants respectfully request that claims 101 and 102 to the non-elected species be rejoined, examined, and allowed. *See*, 37 CFR § 1.141.

Reexamination of the application and reconsideration of the rejections and objections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

### **I. Preliminary Remarks**

Applicants acknowledge and thank the Examiner for returning an initialed and signed copy of the Information Disclosure Statements submitted 10/18/07, 12/27/07 and 1/17/08.

### **II. Interview Summary**

Applicants thank Examiners Chandra and Landsman for their courtesy extended during an interview with Applicants' representative, Joshua Elliott, on July 9, 2008. During the interview, Applicants' representative appreciated the opportunity to discuss the cited reference (U.S Patent No. 5,888,511).

### **III. Claim Objections**

Claims 81 and 100 have been objected to in the Office Action for reciting non-elected subject matter. Applicants note that claim 81 has been canceled without prejudice to or disclaimer of the underlying subject matter, and therefore the objection with regard to claim 81 is moot. With respect to claim 100, the elected and non-elected species are encompassed in independent claim 99, from which claim 100 depends. The Office has previously stated that "upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided in 37 CFR 1.141." *Office Action* dated

August 23, 2005, at page 2. As such, Applicants respectfully request that the objection be held in abeyance until allowance of generic claim 99.

#### **IV. Claim Rejections Under 35 U.S.C. § 102(b)**

Claims 80-81, 85-92, and 96-100 remain rejected under 35 U.S.C. § 102 as being anticipated by Skurkovich et al. (U.S. Patent No. 5,888,511). The rejection of claims 80-81, 85-92, and 96-98 is moot as claims 1-98 have been canceled without prejudice to, or disclaimer of the underlying subject. The rejection of claims 99 and 100 is traversed for at least the following reasons.

The Office Action alleges that Applicants' previous arguments with regard to claim 99 were not persuasive because the Skurkovich et al. reference allegedly teaches "treating an autoimmune disease 'Ankylosing Spondylitis' by administering an anti-IFN- $\alpha$  (see Example 3 and Table 2)." *Office Action*, at page 5.

Contrary to the Examiner's allegations, Example 3 of Skurkovich et al. does not disclose such a method for treating ankylosing spondylitis (or other autoimmune diseases encompassed by claim 99) consisting of administration of a composition consisting of humanized or human monoclonal antibodies (or antigen-binding fragments thereof) against IFN- $\alpha$  alone (i.e., as the sole active ingredient) and the one or more of the other recited components, where the autoimmune disease is not rheumatoid arthritis, Acquired Immune Deficiency Syndrome (AIDS), or diabetes.

As explained in the Examiner Interview on July 9, 2008, Example 3 of Skurkovich et al. discloses that four groups of human subjects having severe rheumatoid arthritis were treated with either anti-TFN $\alpha$  antibodies (Group A), anti-IFN $\alpha$  antibodies (Group B), anti-IFN $\gamma$  antibodies (Group C) or a combination of anti-TFN $\alpha$  antibodies, anti-IFN $\alpha$  antibodies, and anti-IFN $\gamma$  antibodies (Group D). *Col. 24, line 64 through Col. 25, line 7*. The Example discloses that the subjects used in these treatment groups were between the ages of 27-64. *Col. 24, lines 65-66*. Table 2 shows the proportion of patients achieving  $\geq 20\%$  improvement in the Paulus measures (which included morning stiffness, number of painful and inflamed joints, ESR, etc.) for these treatment groups. *Col. 25, lines 34-36*.

Example 3 goes on to discuss the treatment of a single ankylosing spondylitis patient that was 22 years old using a combined antibody regimen (antibodies to IFN $\alpha$ , IFN $\gamma$ , and TFN $\alpha$ ) ("One ankylosing spondylitis ('AS') patient, age 22, disease duration one year, was treated with the combined antibody regimen (antibodies to IFN $\alpha$ , IFN $\gamma$ , and TNF $\alpha$ )"). *Col.*

26, lines 25-27. Because this one ankylosing spondylitis patient was of an age (22 years old) outside the age range identified for the rheumatoid arthritis subjects (27-64 years old), the ankylosing spondylitis patient could not have been one of the subjects tested in one of the rheumatoid arthritis groups. No other ankylosing spondylitis patients are discussed in Example 3. Thus, Example 3 does not disclose treating an ankylosing spondylitis patient with anti-IFN $\alpha$  alone. Accordingly, Example 3 in Skurkovich et al. cited by the Examiner does not disclose or suggest treating autoimmune diseases using the method of claim 99 consisting of administration of a composition consisting of humanized monoclonal anti-IFN $\alpha$  antibodies (or antigen-binding fragments thereof) and the one or more of the other recited components, where the autoimmune disease is not rheumatoid arthritis, Acquired Immune Deficiency Syndrome (AIDS), or diabetes.

Therefore, because all of the features of claim 99 are not taught in Skurkovich et al., independent claim 99 and dependent claims 100-103 are not anticipated, and Applicants respectfully request reconsideration and withdrawal of the rejection.

For the foregoing reasons, claims 99-103 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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